## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE (Case No. 97-022-D1CO)

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Alexandria, VA 22313-1450

## REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. 1.705 (b)-(d)

Sir:

Responsive to the Determination of Patent Term Adjustment posted on the Patent Application Information Retrieval System (PAIR) as of the December 14, 2010 issue date of U.S. Patent No. 7,853,411 ('411), and in light of the recent ruling in *Wyeth v. Dudas*, No. 07-1492, slip op. (D.D.C. Sept. 30, 2008) the Patentees submit this Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. 1.705(b)-(d) along with the required fee set forth in 1.18(e). As stated in 37 C.F.R. 1.705(d):

If the patent indicates or should have indicated a revised patent term adjustment, any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and must comply with the requirements of paragraphs (b)(1) and (b)(2) of this section. Any request for reconsideration under this

section that raises issues that were raised, or could have been raised, in an application for patent term adjustment under paragraph (b) of this section shall be dismissed as untimely as to those issues.

The '411 patent issued on December 14, 2010. This request is being submitted within two months of the issue date of the '411 patent, and complies with the deadline specified in 37 C.F.R. 1.705(d). In addition, given that the final determination of Patent Term Adjustment and the inclusion of "B delay" is not set until issuance, Patentees could not have raised this issue prior to payment of the issue fee. Thus, Patentees contend this request is timely.

The data available on PAIR indicates that the '411 patent has been granted a 1340 day Patent Term Adjustment. Patentees submit that the correct Patent Term Adjustment should be 1649 days. Patentees, therefore, request that the '411 patent be granted an additional 309 (1649 - 1340 = 309) days of patent term.

Patentees agree with the Patent Office's initial determination, which, for purposes of this request and in keeping with the explanation provided in *Wyeth*, Patentees will refer to as the "A delay" and "C delay." In the "A delay" the Patent Office delayed prosecution by issuing the first communication 14 months plus 366 days after the filing of the application (37 CFR 1.703(a)(1)). The Patent Office was also responsible for a "C delay" by issuing the BPAI decision 624 days after the filing of the Notice of Appeal (37 CFR 1.703 (e)). Therefore the Patent Office was responsible for a total "A delay" of 366 days and a "C delay" of 624 days for a total of 990 (366 + 624 = 990) days delay.

In the "A delay" the Patentees delayed prosecution by filing a response to an Office Action 3 months plus  $\underline{53}$  days after the mailing of the respective action (37 CFR 1.704(b)) and by twice filing a non-responsive amendment; the first time was  $\underline{29}$  days after the filing of the original Response and the second time was  $\underline{33}$  days after the filing of the second Response (see 37 CFR 1.704(c)(7)). The Applicant was responsible for two more delays; by filing a Response to an Office Action 3 months plus  $\underline{62}$  days after the mailing of the respective Action, and by filing a Notice of Appeal 3 months plus  $\underline{61}$  days after the mailing of the respective Action (see 37 CFR 1.704(b)). Therefore the Applicants were responsible for a total "A delay" of  $\underline{238}$  (53 + 29 + 33 + 62 + 61 = 238) days delay.

These combined delays result in an "A delay" and "C delay" of <u>752</u> days (990 – 238 = 752) and Applicants' calculations are in agreement with the Patent Office regarding the "A" and "C" delays.

The Patent Office however has miscalculated the Patent Term Adjustment days related to the "B delay," which are the days delay resulting from an application pending longer than three years. According to 37 C.F.R. 1.703(b):

The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued, but not including the sum of the following periods:

4) The number of days, if any, in the period beginning on the date on which a notice of appeal to the Board of Patent Appeals and Interferences was filed under 35 U.S.C. 134 and § 41.31 of this title and ending on the date of the last decision by the Board of Patent Appeals and Interferences or by a Federal court in an appeal under 35 U.S.C. 141 or a civil action under 35 U.S.C. 145, or on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first, if the appeal did not result in a decision by the Board of Patent Appeals and Interferences.

Currently the Patent Office has calculated the "B delay" to be 588 days; Applicants respectfully believe this to be an error. As noted in 37 CFR 1.703(b) and 1.703(b)(4) the "B delay" runs from "the date that is three years after the date on which the application was filed" until the date of issuance but does not include "the number of days in the period beginning on the date on which a notice of appeal to the Board of Patent Appeals and Interferences was filed and ending on the date of the last decision by the Board of Patent Appeals and Interferences." The instant application was filed on October 15, 2003 and a Notice of Appeal was filed on November 10, 2008, which is 3 years plus 756 days

after the filing date. The "B delay" then continues after the mailing of the BPAI decision on July 26, 2010 until the date of issuance on December 14, 2010, resulting in an additional "B delay" of  $\underline{141}$  days. Thus, the total "B delay" is  $\underline{897}$  days and NOT 588 as asserted by the Patent Office (756 + 141 = 897)

Thus, the total Patent Term Adjustment due to the "A," "B," and "C" delays and minus the Applicants' "A" delay is 1649 days (366 + 897 + 624 - 238 = 1649).

For these reasons, the Patent Term Adjustment for this case should be 1649 days.

In light of the foregoing, the Patentees respectfully request that an additional 309 days of Patent Term Adjustment be added to the patent term for Patent Office delay, resulting in a total Patent Term Adjustment of 1649 days. If a telephone conference would expedite the prosecution of this Request for Reconsideration of Patent Term Adjustment, please contact the undersigned agent as indicated below.

Respectfully submitted,

Date: December 14, 2010 /Isadora F. Bielsky/

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